UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MARY BAYES and PHILIP BAYES, Plaintiffs, v. BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, BIOMET MANUFACTURING, LLC f/k/a BIOMET MANUFACTURING CORP., Defendants.	Case No. 4:13-cv-00800-SRC

MEMORANDUM IN SUPPORT OF DEFENDANTS' OMNIBUS MOTIONS *IN LIMINE*

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MIL No. 1. Exclude evidence of other complaint files, claims, and lawsuits.

The Court should preclude Plaintiffs from introducing evidence of other complaint files, claims, and lawsuits[1] because: (1) they are irrelevant and hearsay; and (2) they are not admissible as other substantially similar incidents.[2]

A. Complaint files, claims, and lawsuits are irrelevant and hearsay.

Evidence of other complaint files, claims, and lawsuits is irrelevant and inadmissible hearsay. Allegations of defects in products *other than* the M2a Magnum should be excluded because they are in no way probative of whether a defect existed in Ms. Bayes's M2a Magnum components. *See* FRE 402. Further, complaint files, claims, and lawsuits involving the M2a Magnum are only *claims*, and claims are not relevant or competent as evidence. *See J.B. Hunt Transp., Inc. v. Gen. Motors Corp.*, 52 F. Supp. 2d 1084, 1089 (E.D. Mo. 1999) ("To simply state that an accident occurred, a lawsuit was filed and the lawsuit was concluded in some manner or other fails entirely to meet plaintiffs' evidentiary burden.") *aff'd*, 243 F.3d 441 (8th Cir. 2001).[3] Other complaints, lawsuits, and claims also are inadmissible hearsay. *See C.C. through Ginnever v. Suzuki Mfg. of Am. Corp.*, 2018 WL 4504687, at *2 (E.D. Mo. 2018) (excluding claims because "the information within the claims is hearsay without an applicable exception"); *Rodrick v. Wal-Mart Stores East, L.P.*, 2009 WL 10672554, at *6 (W.D. Mo. 2009) (same).

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1 Based on exhibits used during Biomet's employees' depositions, Plaintiffs may attempt to introduce compilations of complaint files or lawsuits. *See, e.g.*, Ex. A, Thacker Dep. Ex. 71 (M2a complaint spreadsheet); Ex. B, Thacker Dep. Ex. 68 (M2a-38 complaint spreadsheet); Ex. C, Plfs' Rule 26 Discl. (identifying Thacker as a fact witness).

2 Some exhibits used during common issue depositions are compilations which compound the risk of juror confusion and cannot be considered as other similar incident evidence. *See* Ex. D, Naylor Dep. Ex. 5 (MoM Complaints, see rows 1 [involving an M2a-38 modular head], 15 [primary complaint "Range of motion problems"], 18 [components identified as "M2a-38 from Finland"]). These types of documents should be excluded on multiple grounds.

3 *See also Skibniewski v. Am. Home Prods. Corp.*, 2004 WL 5628157, at *11 (W.D. Mo. 2004) ("[O]ther lawsuits, claims and settlements are irrelevant and inadmissible to show that [defendant] was liable for plaintiff's injuries").

B. No complaint files, lawsuits, or claims are substantially similar to Ms. Bayes's clinical experience with the M2a Magnum.

Introducing other patients' complaint files, lawsuits, and claims would confuse the issues in Ms. Bayes's case, waste time, and unfairly prejudice Biomet. The Eighth Circuit has repeatedly emphasized that "admitting similar-incident evidence carries the risk of raising 'extraneous controversial points, lead[ing] to a confusion of the issues, and present[ing] undue prejudice disproportionate to its usefulness.'" *Adams v. Toyota Motor Corp.*, 867 F.3d 903, 914 (8th Cir. 2017) (quoting *First Sec. Bank v. Union Pac. R.R. Co.*, 152 F.3d 877, 879–80 (8th Cir. 1998)) (alterations in original). Accordingly, the bar to introducing other similar incidents is high, and the proponent must demonstrate that the evidence is "of like character, occurring under substantially the same conditions, and it must be one resulting from the same cause." *Rodrick*, 2009 WL 10672554, at *6 (internal quotations omitted). Indeed, federal courts in Missouri have required plaintiffs to disclose to the court the allegedly related cases or claims they intend to introduce before the jury is seated to avoid any prejudice to defendant. *See id.*[4] Plaintiffs cannot establish that any complaint files, claims, or lawsuits are sufficiently similar, and they should be excluded.

1. Complaint files, claims, and lawsuits regarding other hip replacement products[5] are not substantially similar as a matter of law.

Claims involving other hip replacement products are not sufficiently similar to Ms. Bayes's case. *See* FRE 402–03. Permitting such evidence would confuse and mislead the jury from its task of identifying whether there was a defect in (or Biomet was negligent related to) Ms. Bayes's M2a Magnums that caused her claimed injury. Claims involving other products (whether Biomet

[4] Defendants respectfully request that, if Defendants' MIL 1 is not sustained in full, the Court establish a procedure whereby Defendants can object to the introduction of such evidence outside the presence of the jury.

[5] *See, e.g.*, Ex. E, Lancaster Dep. Ex. 6 (DePuy weekly complaint listing); Ex. C, Plaintiffs' Rule 26 Disclosures (listing Jim Lancaster as a potential fact witness); Ex. F, Kantor Dep., 79:25–80:2 (refers to DePuy litigation, Pinnacle and ASR recalls); 145:7–9 (refers to Zimmer's Durom MoM hip recall).

products or other manufacturers' MoM[6] hips) are not of like character, did not occur under substantially the same conditions, and are irrelevant. *See, e.g., Katzenmeier v. Blackpowder Prod., Inc.*, 628 F.3d 948, 951 (8th Cir. 2010) (holding incidents involving different manufacturer were not substantially similar); *cf.* Doc. 163, Order (finding attorney's work on Zimmer's MoM litigation was not "substantially related" to this case). Allegations related to unrelated products are not probative of whether Ms. Bayes's M2a Magnum components were defective or caused injury, and the Court should exclude them. *See* FRE 402.

2. Foreign complaint files, claims, and lawsuits are not substantially similar to Plaintiffs' case and raise heightened risks of unfair prejudice.

Evidence of foreign complaints, claims, or lawsuits is irrelevant, will muddy the issues and legal standards, and lead to jury confusion.[7] FRE 401–03. As many courts have recognized, products liability claims should be judged by American standards, not the different legal standards of foreign regulators or judicial systems. *See, e.g., Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006) ("American regulators have different priorities and deal with often more diverse populations than their European counterparts. The issue is whether the United States label. . . provides adequate instructions. . ."). [8] The different standards applicable to foreign claims and complaints magnifies the potential for such evidence to confuse the issues and mislead the jury, *see* FRE 403, regarding the questions of defect and causation. What constitutes a defect or

[6] Defendants use "MoM" to refer to metal-on-metal articulating hip implants.

[7] *See, e.g.*, Ex. A, Thacker Ex. 71, at row 5 (providing information on complaint from Finnish hospital Lapin Keskussairaala that was investigated by Biomet UK); Ex. G, Miller Dep. Ex. 57 (EU Reportable complaints); Ex. C, Plfs' Rule 26 disclosures (identifying Katie Miller as a potential fact witness).

[8] *See also Harrison v. Wyeth Labs.*, 510 F. Supp. 1, 4–5 (E.D. Pa. 1980), *aff'd*, 676 F.2d 685 (3d Cir. 1982) ("Each government must weigh the merits of permitting the drug's use and the necessity of requiring a warning . . . [F]airness to the defendant mandates that defendant's conduct be judged by the standards of the community affected by its actions"); *In re Viagra Prods. Liab. Litig.*, 658 F.Supp. 2d 950, 965 (D. Minn. 2009) (excluding "any discussion of foreign regulatory actions" as "irrelevant" and otherwise unfairly prejudicial).

legal cause in a foreign country may not be considered a defect or legal cause in Missouri. Therefore, this evidence should be excluded.

3. Plaintiffs cannot establish that any M2a Magnum complaint files, claims, or lawsuits are substantially similar to Plaintiffs' case.

A variety of factors may lead to a hip implant failing and Plaintiffs have no basis to introduce evidence that another patient's injuries were the same as Ms. Bayes's. *See Rodrick*, 2009 WL 10672554, at *6 (similar incident evidence "must be one resulting from the same cause"). The introduction of evidence of other M2a Magnum complaint files, claims, or lawsuits would compel Biomet explain to the jury the differences between those patients and Ms. Bayes. These "mini-trials" will prolong trial, require causation opinions regarding each patient's reported injuries, and introduce evidence that is irrelevant to Plaintiffs' case. This evidence would "confuse and mislead the jury" from its task of finding the cause of Ms. Bayes's injuries and should be excluded. *See id.* (excluding references to other cases and claims);[9] FRE 403.

MIL No. 2. Exclude evidence of M2a marketing materials and references to Mary Lou Retton.

M2a marketing materials are irrelevant because Plaintiffs never saw marketing materials, and Ms. Bayes's implanting surgeon, Dr. Martin, did not change his practice based on marketing materials. *See* FRE 401, 402.[10] Any arguable relevance of M2a marketing materials and topics related to Biomet's M2a marketing (including Biomet's business relationship with Ms. Retton) is outweighed by the risk of confusing the issues, misleading the jury, and wasting time on evidence that had *no i*mpact Ms. Bayes's treatment. *See* FRE 403.

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[9] *See also Brennan v. Paul Revere Life Ins. Co*., 2002 WL 1284385, at *4 (N.D. Ill. 2002) ("extraordinary confusion of the issues" would result if other lawsuits were introduced); *Estates of Tobin v. Smithkline Beecham Pharm.*, 2001 WL 36102165, at *1 (D. Wyo. 2001) (other lawsuits related to drug would unnecessarily confuse jury).

[10] Doc. 148, Pltfs' SUMF Resp., at ¶¶ 8, 10, 29.

First, Dr. Martin did not select the M2a Magnum based on Biomet's marketing materials,[11] and there is no evidence that Dr. Martin saw any advertisements. Thus, introduction of advertisements will only waste time, confuse the issues, and mislead the jury. *See* FRE 403.

Second, Plaintiffs cannot use marketing materials involving former Olympic gymnast Mary Lou Retton to "back door" in evidence of Ms. Retton's personal lawsuit[12] and settlement. FRE 408.[13] Therefore, and as explained in MIL 1, Biomet respectfully requests an order excluding Biomet's advertisements featuring Ms. Retton, her lawsuit, and eventual settlement because any alleged relevance is substantially outweighed by the risk of unfair prejudice that the jury's decision will be improperly influenced by hearing that a former Olympic athlete reported complications with the M2a Magnum. *See* FRE 403.

Evidence of Biomet's marketing should be excluded because it *did not* affect Ms. Bayes's care and it will prolong trial and confuse issues properly before the jury. *See* FRE 402–03.

MIL No. 3. Exclude evidence of events, documents, and statements unrelated to Plaintiffs that post-date Ms. Bayes's April 28, 2008 left hip implant surgery.

Plaintiffs intend to introduce considerable evidence concerning events, conduct, and knowledge that occurred after — and sometimes long after — Ms. Bayes's 2008 M2a Magnum implant surgeries.[14] The Court should exclude such evidence because (1) it is irrelevant, (2) it carries a high risk of confusing the jury, and (3) it constitutes inadmissible subsequent remedial measures.

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[11] Ex. H, Martin Dep. 11:13–20.

[12] Ms. Retton's revision surgery and lawsuit post-date Ms. Bayes's revision surgeries. Ms. Retton alleged her M2a Magnum hip system was revised after 10 years due to elevated chromium and cobalt levels. *See* Ex. I, Retton Compl, at ¶¶ 20, 22, 26, 28. Ms. Bayes's left hip revision surgery, the primary focus of her lawsuit, was performed after less than 3 years because of a vertical acetabular cup, not because of elevated cobalt or chromium levels.

[13] *See* Ex. J, Glock Dep. 211:22–215:7 (discussing Ms. Retton's post-surgical course).

[14] *See, e.g.*, Doc. 1, Compl., at ¶ 24; Doc. 148, Pltfs' SUMF Resp., at ¶ 181.

First, evidence of Biomet's conduct or knowledge that post-dates Ms. Bayes's implant surgeries in 2008 is irrelevant because the "operative reference point" for products liability claims is the time of sale of the product. *See Bachtel v. Taser Intern'l, Inc.*, 2013 WL 317538, at * 6 (E.D. Mo. 2013) (citing *Moore v. Ford Motor Co.*, 332, S.W.3d 749, 756 (Mo. banc 2011)).[15] Therefore, any events that occurred after Ms. Bayes's April 28, 2008 M2a Magnum left hip implant surgery (the later of her two implant surgeries) is irrelevant and cannot establish liability under Missouri law. *See generally* Mo. Rev. Stat. § 537.760(3) (claimants must show the product was in a "defective condition *as existed when the product was sold"* or was "unreasonably dangerous *when put to a reasonably anticipated use*" (emphasis added)); *Id.* § 537.764(1) ("the time the product *was placed into the stream of commerce*" is the reference point for state of the art defense).[16]

Second, even if evidence that post-dates Ms. Bayes's 2008 surgeries was arguably relevant, it should be excluded to prevent confusing the issues and misleading the jury regarding Biomet's knowledge. *See* FRE 403. Documentation that post-dates Ms. Bayes's surgeries is voluminous and could overwhelm the evidence of what Biomet knew when Ms. Bayes's device was sold. Plaintiffs cannot impose a duty on Biomet based on information that did *not* exist in 2008. For example, Plaintiffs should not be allowed to rely on evidence of a 2016 FDA inspection at a Biomet facility because Ms. Bayes's M2a Magnum devices had been explanted by that time.[17] Evidence that post-

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[15] *See generally* Doc. 125, Defs' MSJ Memo, at 12–13, 26; *see also Howerton v. Blitz USA, Inc.*, 2008 WL 11338463, at *7 (W.D. Mo. 2008) (limiting evidence of changes after product was placed in the stream of commerce); *Pitman v. Ameristep Corp.*, 208 F. Supp. 3d 1053, 1060, 1062 (E.D. Mo. 2016) (design defect and failure to warn are evaluated based on the design and warnings provided "at the time of sale"); *Mouser v. Caterpillar, Inc.*, 2000 WL 35552637, *17 (E.D. Mo. 2000) (breach of implied warranty of merchantability is determined "at the time of the sale"); Doc. 125, Defs' MSJ Memo, at 12–13, 26

[16] Defendants have pled state of the art as an affirmative defense.

[17] Additionally, Plaintiffs argue the September 2011 IFU "spell[ed] out the metal-on-metal specific risks of [Biomet's] devices," but the 2011 IFU incorporates the April 2010 MHRA Hazard Alert and the February 2011 FDA website, which did not exist at the time of Ms. Bayes's implantation surgeries. *See* Doc. 148, Pltfs' SUMF Resp., at ¶ 181; Doc. 148-21, 2011-09 IFU.

dates Ms. Bayes's surgeries did not impact Ms. Bayes's clinical outcome, so any possible relevance is outweighed by the risk of juror confusion. FRE 403.

Finally, Plaintiffs cannot use evidence of Biomet's actions or knowledge that post-dates Ms. Bayes's implantation surgeries because such information is inadmissible as evidence of subsequent remedial measures under Rule 407.[18] The Court should prevent Plaintiffs from using subsequent iterations of Biomet's IFUs, product withdrawals, or other communications with surgeons to establish defect, negligence, culpable conduct, or a need for a warning or instruction.[19] *See Cowden*, 980 F. Supp. 2d at 1111.

MIL No. 4. Exclude evidence concerning Biomet's deferred prosecution agreements with the Justice Department and related documents.

Evidence of or reference to the 2007 Deferred Prosecution Agreement ("2007 DPA") and the 2012 Deferred Prosecution Agreement ("2012 DPA") between Biomet and the United States government and related documents are irrelevant, unduly prejudicial, and constitute inadmissible character evidence.[20] In March 2005, the U.S. Attorney's Office for the District of New Jersey ("USAO") commenced an industry-wide investigation into hip and knee manufacturers' consultant-hiring practices. The USAO subpoenaed five of the largest hip and knee orthopedic manufacturers, including Biomet, requesting consulting contracts and professional service and remuneration agreements between the companies and healthcare professionals. The investigation had nothing to do with product safety or product liability.[21] To resolve this investigation, Biomet

[18] The 1997 FRE amendments "adopt[ed] the view of the majority of the circuits that have interpreted Rule 407 to apply to products liability actions." FRE 407 advisory comm. notes. Since this amendment, courts in the Eighth Circuit have applied Rule 407 to negligence and strict liability claims. *See Norman v. Textron Inc.*, 2018 WL 3199496, at * 2, (W.D. Mo. 2018); *Cowden v. BNSF Ry. Co.*, 980 F. Supp. 2d 1106, 1111 (E.D. Mo. 2013); *cf. Lopez v. Tyson Foods, Inc.*, 690 F.3d 869, 882–83 (8th Cir. 2012) (no plain error in applying FRE 407 in a strict liability case in light of the 1997 amendment to FRE 407).

[19] *See* Doc. 148, Pltfs' SUMF Resp., at ¶ 19.

[20] *See* Ex. K, 2007 DPA, Ex. L, 2012 DPA, Ex. M, Settlement Agreement between the US government and Biomet, Inc.

[21] *See* Ex. K, at ¶ 2.

and the other manufacturers adopted certain consultant-hiring reforms and reforms related to hiring physician consultants.[22] Similarly, Biomet entered into the 2012 DPA, which was primarily related to hip orthopedics products sold in Brazil and Mexico, including allegations that Biomet had violated the Foreign Corrupt Practices Act.[23]

The DPAs are irrelevant to Plaintiffs' claims. Indeed, the 2007 DPA expressly states that neither the 2007 DPA nor the government "alleges [that Biomet's] conduct adversely affected patient health or patient care."[24] The Court should exclude evidence or argument regarding these agreements as irrelevant. *See* FRE 401, 402; *Smith v. Toyota Motor Corp.*, 2018 WL 1806698, at *5 (E.D. Mo. 2018) (excluding evidence regarding DPA).[25]

Moreover, the DPAs are unduly prejudicial and constitute improper character evidence. *See* FRE 403, 404. Plaintiffs' only possible purpose in offering these documents is to ask the jury to infer that, because Biomet agreed to modify its conduct in a completely unrelated context, the company must have behaved improperly in this case — which is impermissible character evidence. FRE 404. Any arguable probative value the DPAs have is substantially outweighed by the harm of unfair prejudice and confusion of the issues before the jury. FRE 403.

MIL No. 5. Exclude evidence or argument linking the M2a Magnum to alleged risks and complications that Plaintiff Mary Bayes did not experience.

Evidence of risks and complications that Ms. Bayes never experienced with her M2a Magnums is irrelevant and unfairly prejudicial. *See* FRE 402–03. For example, Plaintiffs should be precluded from alleging that the M2a or MoM hips can cause cold welding, taper corrosion,

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[22] *See* Ex. K, Ex. M.
[23] *See* Ex. L.
[24] Ex. K, at ¶ 2.
[25] *See also In re Oil Spill by the Oil Rig DEEPWATER HORIZON in the Gulf of Mexico, on Apr. 20, 2010*, No. MDL 2179, 2012 WL 425164, at *3 (E.D. La. 2012) (excluding evidence of DPA where conduct addressed by DPA was dissimilar from and not relevant to the issues at trial); *see also Med. Sales & Consulting Grp. v. Plus Orthopedics USA, Inc.*, 2011 WL 1898600, at *1-2 (S.D. Cal. 2011) (excluding evidence regarding DPA between Smith and Nephew and the USAO—the same DPA at issue here).

infections, or systemic complications and malignancies because there is no evidence that Ms. Bayes experienced these complications.[26] *See* FRE 402.

Any arguable relevance of admitting evidence of the risks Ms. Bayes did not experience is substantially outweighed by the evidence's potential to unfairly prejudice Biomet through confusing the issues, misleading the jury, and wasting time. *See Dean v. Am. Home Prods. Corp.*, 2007 WL 2030238, at * 1 (E.D. Mo. 2007) (excluding evidence of a medical condition that plaintiff had not been diagnosed with as "separate and apart from . . . the injury alleged in this case").[27] Evidence of unrelated complications would cause the jury to lose sight of the injuries Ms. Bayes allegedly experienced. Therefore, the Court should exclude such evidence.

MIL No. 6. Exclude evidence of foreign regulatory actions, presentations, and communications.

Plaintiffs' evidence should be limited to evidence of Biomet's activities and sales communications *in the United States* that are relevant to Plaintiffs' claims. Plaintiffs have identified multiple witnesses[28] who were involved primarily with Biomet's activities overseas. Biomet's activities in other countries are irrelevant, unduly prejudicial, and, in some instances, are subsequent remedial measures. *See* FRE 402–03, 407.

A. Foreign regulatory actions and product withdrawals are irrelevant and unfairly prejudicial.

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[26] *See* Ex. N, Truman Dep. 171:1–20, 261:21–262:8 (cold welding); *Id.* at 150:6–25, 168:1–13 (taper corrosion), Ex. O, Gannon Common Issue Report, at 1 (infections late in their postoperative course); Ex. P, Kantor Common Issue Report, at 16 (late, acute infections); Ex. Q, Kantor Rebuttal Report, at 13–14 (systemic complications and malignancies).

[27] *See also Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 564 (W.D. Pa. 2003) (excluding expert testimony that a drug "causes strokes different than the kind that plaintiff experienced" because it did not fit the facts of the case); *Wolf ex rel. Wolf v. Proctor & Gamble Co.*, 555 F. Supp. 613, 622 (D.N.J. 1982) (excluding evidence of non-Toxic Shock Syndrome because of "the danger that in considering these other complaints, the jury might confuse the issues in the case and lose sight of the actual injury being litigated"); *cf. In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536876, at *4, (S.D.W.V. 2016) (excluding general causation evidence from MDL regarding infections, fistulae, and abscesses because "the relevant plaintiffs did not experience the discussed complications").

[28] *See* Ex. A, Pltfs' Rule 26 Discl. (identifying Oliver Barass, Eline Harting, Dr. Stephen Graves, and David Stephenson as fact witnesses); Ex. R, Harting Dep. at 11:9–14:20.

Evidence of foreign regulatory actions and product withdrawals – including characterizing these actions, which all post-date Ms. Bayes's 2008 implantation surgeries, as "recalls"– has no probative value and carries a strong risk of unfair prejudice to Biomet.[29] Additionally, product withdrawals from the market are inadmissible subsequent remedial measures under Rule 407.

Foreign regulatory actions concerning the M2a Magnum are irrelevant to Ms. Bayes's claims and are inadmissible under Rule 402. Ms. Bayes's treatment occurred in Missouri before any foreign regulatory action was taken or the M2a Magnum was withdrawn from any foreign (or domestic) market. Therefore, these regulatory actions did not inform Dr. Martin's decision to select the M2a Magnum for Ms. Bayes's hip replacements or impact Dr. Lux or Dr. Nunley's decisions to perform revision surgeries in 2011 and 2014, respectively.

Evidence of foreign regulatory actions should also be barred under Rule 403 because such evidence will confuse and mislead a jury. If such evidence is allowed, Biomet will have to distinguish the foreign regulatory standards from the U.S. regulatory standards, which would waste time and distract the jury from the issues at hand. *See* FRE 403.[30]

Additionally, evidence of Biomet's withdrawal of the M2a Magnum from foreign markets is inadmissible to prove liability under Rule 407, which bars evidence of subsequent remedial measures. For all these reasons, Plaintiffs should be barred from introducing evidence of Biomet's withdrawal of the M2a Magnum from foreign markets and foreign regulatory actions.

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[29] The two primary regulatory actions or publications are (1) the Australia Therapeutic Goods Administration February 9, 2015 "Hazard Alert" concerning M2a Magnum and M2a-38 devices, and (2) the April 12, 2016 MHRA Urgent Field Safety Notice. *See* Ex. S, TGA Hazard Alert; Ex. T, Urgent Field Safety Notice. The Urgent Field Safety Notice involved the M2a-38, a different Biomet product, but Plaintiffs have attempted to use M2a-38 documents to support their claim punitive damages. *See* Doc. 167, Defs' SUMF Reply, at ¶¶ 186–87. Neither document constituted a recall. *See, e.g.*, Therapeutic Goods Administration, "About Australian recall actions" at https://www.tga.gov.au/about-australian-recall-actions (last visited August 5, 2020) (stating a "hazard alert" "is issued for an implanted therapeutic good . . . [that] cannot be recalled").

[30] *See Deviner v. Electrolux Motor*, 844 F2d, 769, 773 (11th Cir. 1988) (evidence of foreign law in a products liability case properly barred) *accord Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1327 (6th Cir. 1992).

B. Foreign presentations and communications are irrelevant and unfairly prejudicial.

Biomet's communications and messaging in Europe, Australia, or other countries is irrelevant to Ms. Bayes's case because Ms. Bayes's medical treatment was performed by Dr. Martin, Dr. Lux, and Dr. Nunley in Missouri. *See* FRE 402. Additionally, foreign communications and messaging outside of the United States should be excluded because its alleged probative value, if any, is outweighed by the risk of unfair prejudice to Biomet and juror confusion. *See* FRE 403.

MIL No. 7. Exclude evidence of DePuy Orthopaedic documents, including DePuy documents in Jim Lancaster's custodial file.

DePuy's internal documents, which were produced during discovery, are not relevant to Plaintiffs' claims. Further, design differences between the ASR and M2a Magnum make the DePuy documents unfairly prejudicial and risk jury confusion.

Biomet produced some documents from DePuy as part of Jim Lancaster's custodial file. Jim Lancaster was employed by DePuy until August 2007, when he was hired by Biomet Orthopedics.[31] The emails and documents at issue were largely internal to DePuy and focused on DePuy's MoM hip implant, the ASR.[32] DePuy's design and marketing process of the ASR is not relevant to Plaintiffs' claims. *See* FRE 402.

Evidence about the DePuy ASR cannot establish that the M2a Magnum was defective. *See* FRE 402; *Glass v. Allis-Chalmers Corp.*, 789 F.2d 612, 614 (8th Cir. 1986) (holding plaintiff cannot establish product defect by identifying a class of products that is prone to a specific risk). The ASR and M2a Magnum are different products, developed by different manufacturers, with

[31] *See* Ex. U, Lancaster CV.

[32] *See e.g.*, Ex. V, Lancaster Dep. Ex. 4 (email regarding DePuy's discussion points for MoM); Ex. W, Lancaster Dep. Ex. 5 (email regarding DePuy's MoM proposal and study proposal); Ex. X, Lancaster Ex. 6 (weekly complaint listing for DePuy); Ex. Y, Lancaster Dep. Ex.7 (weekly complaint listing for DePuy) Ex. Z, Lancaster Dep. Ex. 13 (2006 Johnson & Johnson powerpoint titled "WW Hip Development" featuring the DePuy ASR).

different designs and different clinical results.[33] Further, any slight relevance of these documents is substantially outweighed by the risk of juror confusion. *See* FRE 403. This evidence should be excluded. FRE 402–03.

MIL No. 8. Exclude evidence or testimony from Dr. Kantor that Dr. Lewallen's purported relationship with Biomet affected Dr. Lewallen's evaluation of Ms. Bayes.

Dr. George Kantor's personal opinion that Dr. David Lewallen allegedly had a contractual relationship with Biomet that affected Dr. Lewallen's treatment of Ms. Bayes is unfounded and irrelevant, and its admission would confuse and mislead the jury.

Dr. Kantor testified that Dr. Lewallen's evaluation of Ms. Bayes was biased because of compensation Dr. Lewallen allegedly received from Defendants.[34] Despite having met Dr. Lewallen only once,[35] Dr. Kantor testified, "I believe that Dr. Lewallen has disclosures in terms of money received from your company, which I think is important."[36] Despite his lack of personal knowledge (FRE 602), Dr. Kantor claimed Dr. Lewallen's medical record was "self-serving," and that "Dr. Lewallen has been receiving money from Zimmer Biomet for years."[37] But Zimmer Biomet did not exist at the time of Ms. Bayes's March 13, 2015 appointment with Dr. Lewallen and, therefore, any alleged payments he received from Zimmer Biomet could not have influenced Dr. Lewallen's evaluation of Mary Bayes.[38] Dr. Kantor's rank speculation that Dr. Lewallen was biased towards a then-nonexistent company should be excluded because it will not help the jury and is irrelevant. *See* FRE 401–03, 602.

MIL No. 9. Exclude testimony or evidence regarding pre-trial discovery disputes, confidentiality designations, and attorney-client privilege designations.

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[33] *See generally* Ex. AA, Schroeder Dep. 96:17–99:1 (noting design differences between M2a Magnum shell and ASR shell, noting Magnum performed better than ASR).

[34] Plaintiffs' counsel has not identified their source for any of these alleged payments and represent now in their filings that the payments referenced came from *Zimmer Biomet*, not Biomet. *See* Doc. 192, at 2.

[35] Ex. F, Kantor Dep. at 182:17-21; 232:10-13, 233:2-11.

[36] Ex. F, Kantor Dep., at 238:21-239:3.

[37] Ex. F, Kantor Dep. at 242:8-243:20.

[38] Ex. F, Kantor Dep. at 242:8-245:21.

Discovery disputes, confidentiality designations, attorney-client privilege designations, document retention practices, litigation holds, or the Parties' corresponding conduct are irrelevant to Plaintiffs' claims, unfairly prejudicial to Biomet, and may confuse the issues and mislead the jury.[39] Many courts have held that "[e]vidence of discovery disputes between the parties or reference to whether Defendants' production complied with the rules governing discovery are not relevant" to substantive issues. *Barnett v. Gamboa*, 2013 WL 174077, at *2 (E.D. Cal. 2013); *Smith*, 2018 WL 1806698, at *5.[40] This evidence risks inflaming the jury's passions by falsely and inappropriately suggesting that Biomet is attempting to hide the truth from the jury or the Court. Such evidence has no probative value – especially since Plaintiffs had the opportunity to (and did) raise discovery disputes with the Court. *Green v. Baca*, 226 F.R.D. 624, 643 (C.D. Cal. 2005); *see also* FRE 403. Further, such evidence is impermissible character evidence used to suggest Biomet is a bad actor. *See* FRE 404.

By the same analysis, evidence concerning confidentiality and attorney-client privilege designations is irrelevant and inadmissible. Confidentiality and privilege designations carry no weight in supporting or rebutting Plaintiffs' claims or Biomet's defenses, but, if discussed at trial, create a significant risk of unfair prejudice, confusing the issues, and misleading the jury into believing the designations have some bearing on Plaintiffs' claims, which they do not. *See* FRE 402–03. Further, resolving disputes over discovery and confidentiality is the Court's responsibility,[41] not the jury's. In seeking to introduce evidence of discovery and confidentiality

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[39] Defendants do not intend to introduce evidence of discovery disputes or confidentiality or privilege designations.

[40] *See also Datatreasury Corp. v. Wells Fargo & Co.*, 2010 WL 11468934, at *31 (E.D. Tex. 2010) (precluding "testimony, evidence, or argument regarding evidence not produced in discovery in response to a proper discovery request"); *Mformation Techs., Inc. v. Research in Motion Ltd.*, 2012 WL 2339762, at *2 (N.D. Cal. 2012) ("the Court finds good cause to exclude evidence of parties' pretrial discovery disputes," which "are not relevant" to plaintiffs' claims, "and thus should not be presented to the jury").

[41] The Protective Order entered in this matter and Federal Rules of Civil Procedure 26 and 37 set forth procedures for how the Parties must submit discovery disputes and confidentiality challenges to the *Court*.

and privilege disputes in this case or others, Plaintiffs are inviting the jury to find that Defendants violated their duties under the FRCP or a court's orders. The law provides no support for circumventing the Court's authority in this manner.[42]

Additionally, evidence regarding Biomet's document retention or legal hold policies is irrelevant, unfairly prejudicial, and may mislead the jury and confuse the issues. The Court has made no finding of spoliation by Biomet, and Plaintiffs have never argued that Biomet somehow destroyed evidence in bad faith. Biomet's legal hold and document retention practices are therefore irrelevant, and introduction of evidence even hinting at document retention issues or spoliation is improper. *See, e.g., Bundy v. Transp. Desgagnes, Inc.*, 2009 WL 3526189, at *5 (N.D. Ind. 2009) (party seeking adverse inference must present evidence sufficient to support finding that adverse party intentionally destroyed evidence in bad faith) (internal citation omitted). Evidence on these topics has no probative value and would unfairly prejudice Defendants by improperly suggesting that Biomet's document retention practices were inadequate. *See* FRE 403.

MIL No. 10. Exclude evidence of Zimmer's merger with Biomet[43] and related payments.

Evidence or argument regarding Zimmer's merger with Biomet or any payments related to the merger is irrelevant to the issues in this medical device product liability action and its prejudicial effect would far outweigh any arguable probative value.[44] Zimmer merged with Biomet in 2015 – *after* both of Ms. Bayes's M2a Magnum devices had been revised – as part of a complex business transaction. No aspect of the merger, including payments or financial status of either entity or individual alone or combined, has any bearing on Plaintiffs' claims. *See* FRE 402.

Further, any arguable probative value of such evidence is substantially outweighed by the

[42] *See Burwell v. Am. Edwards Labs.*, 574 N.E.2d 1094, 1102 (Ohio Ct. App. 1989) ("We can conceive of no reason why the discovery matters in this case should have been allowed to be presented to the jury.").
[43] This complex business transaction did not directly involve any named Defendant.
[44] *See, e.g.*, Ex. BB, Lancaster Dep. Ex. 34.

risk of severe unfair prejudice to Biomet. *See* FRE 403. Plaintiffs will use this evidence to paint Biomet and Biomet's witnesses as wealthy and biased, engender sympathy for Plaintiffs, and encourage the jury to base its decision on whether Biomet can afford the verdict rather than on whether Plaintiffs have proved their case. Further, discussing a witnesses' financial situation or benefits from an ownership transition would have a harassing or embarrassing effect on a witness. A fundamental principle of American jurisprudence is that "the rich and poor stand alike in courts of justice, and that neither the wealth of one nor the poverty of the other shall be permitted to affect the administration of the law." *E.g.*, *Laidlaw v. Sage*, 52 N.E. 679, 690 (N.Y. Ct. App. 1899).

Courts have long recognized their duty to exclude evidence and improper argument by counsel regarding the alleged wealth or comparative wealth of a defendant based on concerns of unfair passion and prejudice and the Court should exclude such evidence here.[45]

MIL No. 11. Exclude evidence of compensation paid to Biomet's experts in other cases.

Any compensation paid to Biomet's experts in other cases should be excluded because it is irrelevant and is unfairly prejudicial. Expert compensation in other cases is irrelevant to liability and damages, and its introduction would cause unfair prejudice. *See* FRE 401–03. Further, evidence of expert compensation in unrelated cases can improperly provide an avenue to "back door" in evidence that other cases have been filed against Biomet (MIL 1) and Biomet's comparative wealth due to its ability to pay expert witness fees. *See Fassett v. VendTech-SGI, LLC*, 2018 WL 1005561, at * 5 (excluding evidence of Defendant's cost of defense and witness fees). Thus, it should be excluded.

[45] *See Hannan v. Auto-Owners Ins. Co.*, No. 2:13CV00053 ERW, 2014 WL 3701031, at *11 (E.D. Mo. July 25, 2014); *Adams Labs, Inc. v. Jacobs Eng'g Co., Inc.*, 761 F.2d 1218, 1226 (7th Cir. 1985) (appealing to the sympathy of the jurors through references to the wealth of defendants in contrast to the relative poverty of plaintiffs is totally improper and cause for reversal); *Garcia v. Sam Tanksley Trucking, Inc.*, 708 F.2d 519, 522 (10th Cir. 1983); *U.S. v. Stahl*, 616 F.2d 30, 32-33 (2d Cir. 1980); *Draper v. Airco, Inc.*, 580 F.2d 91, 95 (3d Cir. 1978); *Foster v. Crawford Shipping Co.*, 496 F.2d 788, 792 (3d Cir. 1974); *Koufakis v. Carvel*, 425 F.2d 892, 902 (2d Cir. 1970).

Respectfully submitted by:

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CERTIFICATE OF SERVICE

I certify that on August 24, 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the all counsel of record registered to receive electronic Notices of Electronic Filing generated by CM/ECF. Exhibits A, B, C, D, E, G, V, W, X, Y, and Z were filed under seal served via electronic mail.

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